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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,084	02/19/2004	Chung-Sook Kim	HYLEE64.001C1	6252

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,084	KIM ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 6 recite the limitation "said subject" which has no antecedent basis. Claim 11 recites a method wherein the "increase in trabecular bone area is at least about 29 percent." First of all the phrase "at least about," alone, is indefinite. The phrase, "at least about 29 percent" is indefinite. Ranges of more or less than "about" [approximately] are inherently unclear. For example, would that language cover 28%? That is not clear. Since it is less than 29%, it would seem not, but since "about 29%" would cover 28%, and since 28% is "at least" 28%, it would seem that 28% would qualify. See *Ex parte Lee*, 31 USPQ 2nd 1105, 1107; *Amgen vs. Chuggai*, 13 USPQ 2nd 1737, 1787; 18 USPQ 2d 1016, 1030. Deletion of the "about" is suggested.

Furthermore, the apparent written description for this limitation is Table 6, which demonstrates a 29.40 +/- 6.71% change over the control, with this figure being rounded to 29. Leaving aside the inherent indefiniteness of "at least about," it is not clear if the claim requires 29% measured with the same margin of error, or if 22.69% (29.4 – 6.71), or 23%, would suffice. It is also not clear whether the method requires performing a bone biopsy, so that the trabecular bone area may be performed in the same manner, with the same margin of error, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Horcajada-Molteni et al (J. Bone Min. Res., 2000).

Horcajada-Molteni discloses the administration of a composition comprising rutin to inhibit increased bone resorption in OVX rats. See abstract. The reference discloses an increase in bone mineral density but is silent regarding an increase in trabecular bone area. However, Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawruk (US 5,478,579).

Sawruk discloses the administration of a composition comprising isoquercitrin to a patient having osteoporosis. See example I. The reference discloses an increase in bone mineral density but is silent regarding an increase in trabecular bone area. However, Since the Office

does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art, as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 6, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides (US 6,689,748).

Theoharides teaches that mast cell secretion is associated with increased bone resorption and bone loss. See paragraphs bridging col 2-3 and col 3-4. The reference further teaches that flavanoids, such as quercetin inhibit mast cell secretion with a suggested dosage of about 500

mg/day. See col 3, lines 47-59 and col 4, lines 62-65. The reference does not exemplify the administration of quercetin to ameliorate the symptoms of osteoporosis. However, the reference expressly suggests such administration.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer a flavonoid, such as quercetin, to treat osteoporosis. The artisan would reasonably expect success in doing so because the reference expressly suggests such a treatment.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theoharides (US 6,689,748) in view of Jordan (US 4,774,229) and Formica et al (Fd Chem. Toxic., 1995).

Theoharides teaches as set forth above. The reference does not teach the full range of quercetin derivatives set forth in the claims.

Jordan teaches that a wide variety of quercetin derivatives, including glycosides and ethers, are known in the art. See col 2, lines 41-58.

Formica reviews the biology of quercetin and related bioflavanoids. The "Metabolism" section (pp 1063-4) of this reference teaches that the ingested glycosides must be subjected to the action of glycosidases to release the aglycone as the physiologically active form, suggesting that the glycosides are pro-drugs, and that these compounds having the basic quercetin structure, including methoxy derivatives, would have similar physiological activities.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer any quercetin derivative, such as those taught by Jordan, known in the art to a subject for the treatment of osteoporosis. In the absence of unexpected

results, one of ordinary skill would reasonably expect the recited quercetin derivatives to have similar biological activity to quercetin, per se, and have a reasonable expectation of success in administering them to treat osteoporosis.

Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of (1) Horcajada-Molteni et al (J. Bone Min. Res., 2000) or (2) Sawruk (US 5,478,579), in view of Jordan (US 4,774,229) and Formica et al (Fd Chem. Toxic., 1995).

Horcajada-Molteni and Sawruk teach as set forth above. The references do not teach the full range of quercetin derivatives set forth in the claims.

Jordan and Formica teach as set forth above.

Formica reviews the biology of quercetin and related bioflavanoids. The "Metabolism" section (pp 1063-4) of this reference teaches that the ingested glycosides must be subjected to the action of glycosidases to release the aglycone as the physiologically active form, suggesting that the glycosides are pro-drugs, and that these compounds having the basic quercetin structure, including methoxy derivatives, would have similar physiological activities.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer any quercetin derivative, such as those taught by Jordan, known in the art to a subject for the treatment of osteoporosis. In the absence of unexpected results, one of ordinary skill would reasonably expect the recited quercetin derivatives to have similar biological activity to quercetin, per se, and have a reasonable expectation of success in administering them to treat osteoporosis.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

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Leigh C. Maier

Leigh C. Maier
Primary Examiner
June 26, 2006